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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,403	10/01/2003	Sandeep Gulati	VIALO-27	8885
20985	7590	03/25/2005	EXAMINER	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 03/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/677,403	Applicant(s) GULATI, SANDEEP	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 13-20 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to the Amendment received on October 1, 2004.

Preliminary Remark

In view of the IDS received on January 20, 2005, the instant Office Action is necessitated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Claim 2 is drawn to a system that comprises a tessellation means for tessellating the output pattern to facilitate an inteferometric interaction. However, claim 2 does not have any elements or means which conducts interferometric intereaction.

Therefore, the omitted elements are: an inteferometric means (or unit) that generates an interference between the segmented output pattern and a reference wave to enhance the segmented output pattern.

The above is just a suggestion based on the claim language of claim 13.

Applicants are advised to look for proper support in the specification to amend the claims.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a system and a computer product which performs some type of interferometry to amplify signals associated with the biological sample, does not reasonably provide enablement for generic processing to amplify such signals as for example, claim 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

It is noted that instant claims 2, 3, and 5 are directed to the processing of signals from a biological sample which includes intensities both greater and less than the signals associated with noise with amplification of those signals having an intensity lower than signals associated with noise. Marshall (U.S. Patent No. 5,236,826) and Macovski (U.S. Patent No. 4,686,695) are herein cited as describing the problematic situation of noise obscuring biological signals from solid material samples as also instantly claimed as the source of such signals.

Macovski at column 1, line 60, through column 2, line 38, describes biological signal generating systems with explicit discussion of low intensity signals being obscured due to noise. In the abstract, Marshall directs the signal production to correlation with the amount of analyte which is the subject matter of the instant claims directed to determination of specific constituents within a biological sample as in the last 2 lines of instant claim 2 (for example). Noise is cited as interfering, especially with a weak signal, in such assays as discussed in Marshall in column 7, lines 40-45. These references attempt to solve the noise: problems by suppressing the noise producing aspects of the assays and maximizing desired signal strength, but do not indicate what would amplify the desired signals which are less than the noise signal intensity as instantly claimed.

Consideration of the instant disclosure as filed reveals that the amplification of desired signals which have an intensity that is less than noise signals is only described regarding some type of interferometry technique. It is noted that resonance practice, however, is the actual practice of interferometry which is at the basis of the signal amplification practice as instantly disclosed where resonance is well known constructive interferometry. See, for example, the specification on page 9, lines 9-24, wherein the desired signals are produced via convergence (constructive interference).

No other processing of signals methodology has been seen as filed and thus, this scope of enablement rejection is reasonably supported as to undue experimentation to amplify such signals that are less than the noise due to the above art references describing dealing with noise by either noise suppression or desired signal enhancement but without setting forth signal amplification as known in the art thus making it unpredictable to amplify signals out of the noise

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without specific guidance therefor. Only the interferometry type of amplification is instantly set forth thus making only claims limited to this practice enabled and not generic claims that are not so limited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Cabib et al. (U.S. Patent No. 5,784,162, issued July 21, 1998, filed December 12, 1995).

Cabib et al. disclose a method involving:

- a) an optical device, said optical device being optically connected to
- b) an imaging spectrometer, which obtains a spectrum of each pixel of the same by (i) collecting incident light simultaneously from all pixels of the sample using collimating optics;
- c) an interferometer system having a number of elements; and
- d) a detector element (column 7, lines 13-32).

The imaging spectrometer which obtains a spectrum of each pixel would necessarily meet the "preconditioning unit" as the imaging spectrometer preconditions the digitized output (or pixels) for subsequent analysis by the interferometer system.

Double Patenting

The rejection of claims 4 and 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 22 of U.S. Patent No. 6,780,589, issued August 24, 2004, made in the Office Action mailed on September 24, 2004 is withdrawn in view Terminal Disclaimer filed on October 1, 2004.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-28 of copending Application No. 10/616,869, published as US 2004/0111219 A1, published June 10, 2004, made in the Office Action mailed on September 24, 2004 is maintained for the reasons of record.

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Applicants' argument, received on October 1, 2004, state that when the provisional rejection is the only pending rejection in the application, then MPEP 804 instructs that application to issue (page 2, Response).

It appears that Applicants are referring to MPEP 804(I)(B), which discusses provisional double patenting rejection between two copending applications.

MPEP 804(I)(B) states:

"If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent."

The instant application has a filing date of October 1, 2003 while the cited application has a filing date of July 9, 2003. Their earliest effective filing date is also the same - February 22, 1999.

Additionally, the instant application contains rejections under 35 U.S.C. 102 and 103.

Therefore, instant application does not qualify under the instructions set forth in MPEP 804(B)(I) and the provisional rejection is maintained.

Rejections – New Grounds

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 13 of U.S. Patent No. 6,671,625 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1 of the instant application is drawn to a system comprising three elements:

- (a) a preconditioning unit;
- (b) an interferometric unit;
- (c) an analysis unit.

While a preconditioning unit is defined via the phrase, “that *preconditions* the digitized output patterns to facilitate an interferometric interaction,” this phrase does not define what or how the precondition achieves other than **broadly** “facilitating” an interaction.

The ‘625 patent claims a system for analyzing output patterns of arrayed information structure, said system comprising the elements:

- (a) an induction unit for inducing resonances based on interferences between an expression function and spectral characteristics of an arrayed information structure; and
- (b) a detection unit for detecting the presence of the resonance.

Since the induction unit induces resonances based on interferences, such unit would be an interference unit. The detection unit of the ‘625 patent is also equivalent to the analysis unit of the instant application since said detection unit detects the resonances which is based on interferences.

With regard to a preconditioning unit, ‘635 patent describes that a preconditioner converts mutation nucleotide sequences into expected amplitude patterns in the prespecified microarray representation (column 7, lines 43-45).

As claim 7 of the ‘635 patent recites that such a system perform the step of, “processing the output pattern by performing convergent reverberation to yield a resonance pattern representative of resonances between a predetermined set of selected expressor functions and the

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spectral characteristics of the output pattern,” which would render obvious the presence of a system comprising a preconditioning unit that performs this step.

Therefore, the invention as claimed is obvious over the claim of the ‘635 patent.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 25 of U.S. Patent No. 6,136,541. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1 of the instant application is drawn to a system comprising three elements:

- (a) a preconditioning unit;
- (b) an interferometric unit;
- (c) an analysis unit.

While a preconditioning unit is defined via the phrase, “that *preconditions* the digitized output patterns to facilitate an interferometric interaction,” this phrase does not define what or how the precondition achieves other than ***broadly*** “facilitating” an interaction.

The ‘541 patent claims a system for analyzing output patterns of a biochip, said system comprising the elements:

- (a) a resonance pattern for generating a resonance pattern representative of resonances between a stimulus pattern associated with a set of known mutations and the output pattern; and
- (b) a resonance pattern interpretation unit for interpreting the resonance pattern.

Claim 25 recites that the system further comprise an image preconditioning unit.

It is clear that the resonance pattern embraces the process of interferometric resonance (column 8, lines 28-29).

Therefore, the invention as claimed is obvious over claims of the '541 patent.

Conclusion

Claims 1-3 and 5 are rejected.

Claims 4 and 13-20 are free of prior art.

Inquiries

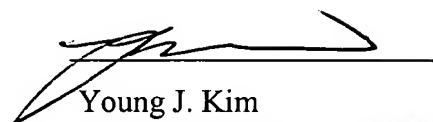
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a

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general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
3/19/05

YOUNG J. KIM
PATENT EXAMINER

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